95141d

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

November 8, 2004

Ref: 2005-DAL-WL-05

WARNING LETTER

Certified Mail
Return Receipt Requested

Laurens A.T.M. Schilderink, President
Spandet Dairy, Inc.
1970 CR 622
Hart, Texas 79043

Dear Mr. Schilderink:

An investigation performed by the U.S. Food and Drug Administration (FDA) included a visit to your dairy operation located at Hart, Texas, June 23-25, 2004. The investigation confirmed that you offered an animal for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigation also revealed that you caused an animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act, because the drug was used in a manner that does not conform with its approved use or the regulations for Extralabel Drug Use in Animals at Title 21, Code of Federal Regulations, Part 530 (21 CFR 530).

Our investigation revealed that your dairy treated a cow with dairy ear tag number 1762 with penicillin G. procaine and sulfadimethoxine. The cow was treated following delivery of her calf for a retained placenta and for diarrhea from January 31, 2004 through February 19, 2004. On February 25, 2004, your dairy shipped the cow to [redacted] The cow was sold on February 26, 2004 and subsequently was offered for slaughter as human food on February 27, 2004, at [redacted] USDA Establishment Number [redacted] USDA analysis (Laboratory Report # 440589) of tissue samples collected from that cow identified the presence of penicillin in the kidney at 0.21 ppm, and sulfadimethoxine in the liver at 0.11 ppm. The tolerance for penicillin is 0.05 ppm in the uncooked edible tissues of

cattle (21 CFR Section 556.510) and the tolerance for sulfadimethoxine is 0.1 ppm in the uncooked edible tissues of cattle (21 CFR Section 556.640).

The presence of these drugs, at the reported levels, in the edible tissues of this animal, cause the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." Our investigation found that you hold animals under conditions which are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, our investigators noted the following:

- You lack an adequate system for assuring that animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

- You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medical records do not include the route of drug administration or dosage administered and do not identify who administered the drug.

In addition, you adulterated penicillin G procaine within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling or on the order of a licensed veterinarian. Your use of this drug without following the dosage level, duration of treatment, frequency of treatment, and withdrawal period of either the approved labeling or the order of your veterinarian causes this drug to be unsafe within the meaning of Section 512 of the Act. Extralabel drug use is permitted only in conformance with all criteria set forth in 21 CFR Part 530, including that there be no residue above established tolerance levels. Because your extralabel use of penicillin resulted in the presence of a residue above the established tolerance, use was not in compliance with the extralabel use regulations. 21 CFR 530.11(d).

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Sherrie L. Krolczyk, Recall and Emergency Coordinator.

Sincerely yours,

Michael A. Chappell
Dallas District Director

MAC:SLK